REMARKS

Applicants wish to thank Examiner Holleran for her time and comments during a telephonic interview with the undersigned representative on May 5, 2005. Possible claim amendments and arguments for rebutting the written description and obviousness rejections were discussed.

Reconsideration of the present application in view of the above amendments and the following remarks is respectfully requested. Claims 1, 2, and 7-21 were pending. Applicants hereby cancel claims 7-17 without acquiescence to any rejection and without prejudice to filing a related divisional, continuation, or continuation-in part application. Applicants have amended claim 1 to define more clearly certain subject matter encompassed by Applicants' invention; these amendments are made without acquiescence to any rejection and without prejudice to filing a related divisional, continuation, or continuation-in part application. Support for the amended claim can be found throughout the specification, for example, at page 17, lines 12-14; page 41, lines 14-22; page 45, lines 11-18; page 61, lines 5-19; page 63, lines 21-24; Table 4; Figure 2, and Figure 7. No new matter has been added. Accordingly, claims 1, 2, and 18-21 are currently pending.

REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH (WRITTEN DESCRIPTION)

Claims 1, 2, and 7-21 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly being directed to subject matter that is not adequately described in the specification. Specifically, the Action alleges that the specification does not describe a genus of seven surface markers selected from the recited group of antigens that would be useful for identifying a type of leukemia in a human subject.

Applicants respectfully traverse this rejection and submit that the specification reasonably conveys to a person skilled in the art that Applicants possessed the claimed invention at the time the application was filed. Applicants respectfully submit that rejection of claims 7-17 is rendered moot by the amendments submitted herewith, which include cancellation of these claims without prejudice.

The present claims are directed to a method for identifying a leukocyte that is of T cell, B cell, or myeloid lineage in a human subject. The method comprises obtaining a biological sample that comprises leukocytes from the human subject, wherein the sample comprises at least one surface marker antigen that is present on the cell surface of a type of leukocyte; contacting the sample with an array of immunoglobulin molecules immobilized to a solid support, wherein the immunoglobulin molecules are specific for surface marker antigens comprising CD3, CD4, CD8, CD14, CD19, and CD56; and determining which surface marker antigens have bound to which immobilized immunoglobulin molecules to establish a discriminatory image of antigen expression and which expression is characteristic of a leukocyte that is of T cell, B cell, or myeloid lineage.

The specification describes a method for identifying and distinguishing different types of leukocytes (*see, e.g.,* specification, at page 44, line 24 through page 45, line 18; page 61, lines 5-19; Table 4; Figures 5 and 7) by obtaining a biological sample that contains leukocytes, which express cell surface marker antigens (*see, e.g.,* specification, page 45, lines 3-18; page 17, lines 12-14, and Figure 2). The sample comprising leukocytes is contacted with an array of immunoglobulin molecules, which are immobilized to a solid support and which are specific for the surface marker antigens, including CD3, CD4, CD8, CD14, CD19, and CD56 that are expressed by leukocytes (*see, e.g.,* page 61, lines 5-19; Table 4; page 17, lines 12-14 and Figure 2). Binding of each immunoglobulin of the array to a cognate cell surface antigen expressed by the leukocytes is then determined, thus providing a discriminatory image of antigen expression, which is a differential pattern of density that is characteristic of a leukocyte that is of T cell, B cell, or myeloid lineage (*see, e.g.,* specification, page 26, lines 11-20; page 39, lines 4-12; page 61, lines 5-19; page 63, lines 21-24; Table 4; Figures 5 and 7). The specification illustrates that a discriminatory image is the relative density of interaction between the antibodies and the cell surface antigens, and which may provide a pattern of expression that can be quantified (*see, e.g.,* specification, page 26, lines 11-20; page 61, lines 5-19; Table 4; Figure 5; Figure 7).

Accordingly, Applicants submit that the instant Application complies with the written description requirement under 35 U.S.C. § 112, first paragraph, and respectfully request that the rejection be withdrawn.

REJECTIONS UNDER 35 U.S.C. § 103

Claims 1, 2, and 18-20 stand rejected under 35 U.S.C. § 103, allegedly for being obvious over Chang (U.S. Patent No. 4,591,570) in view of Terstappen (U.S. Patent No. 5,234,816). The Action also rejects claims 1, 2, and 18-20 for allegedly begin obvious over Chang in view of Verwer (U.S. Patent No. 5,605,805). The Action asserts that Chang teaches that antibodies which bind to cell surface markers may be bound to a solid support for determining whether certain cells will bind to these antibodies. While the Action concedes that Chang fails to teach a method for determining which antigens are expressed on leukemia cells, the Action asserts that Terstappen teaches the relevant antigens for discriminating among different types of leukemias. The Action thus alleges that a person having ordinary skill in the art would have found it obvious to alter the method of Chang to include antibodies that bind to CD antigens for classifying leukemias. The Action notes that the presented arguments are applicable to Chang in view of both Terstappen and Verwer (page 3, lines 5-6).

Applicants respectfully traverse this ground of rejection and submit that the amended claims meet the requirements for nonobviousness. Neither Chang alone, nor Chang in combination with either Terstappen or Verwer, teaches or suggests each and every limitation of the pending claims. Chang fails to teach or suggest a method for identifying a leukocyte that is of T cell, B cell, or myeloid lineage by contacting cells from a human subject with an array of immunoglobulin molecules that are immobilized to a solid surface and that are specific for cell surface marker antigens comprising CD3, CD4, CD8, CD14, CD19, and CD56. Furthermore, none of Chang, Terstappen, or Verwer teaches a method for identifying a leukocyte that is of T cell, B cell, or myeloid lineage, wherein a leukocyte associated with one lineage (*e.g.*, a T cell, B cell, or myeloid lineage) is distinguishable from a leukocyte associated with a different lineage, by determining differential binding density of immunoglobulins to the cell surface marker antigens, CD3, CD4, CD8, CD14, CD19, and CD56.

Chang also fails to suggest, teach, or motivate a person having ordinary skill in the art to combine its teachings with any other prior art teaching to obtain Applicants' presently claimed invention with a reasonable expectation of success. As discussed above, Chang merely

teaches a general method for analyzing multiple antibody-antigen binding interactions and fails to provide any suggestion or motivation for using the method for identifying a leukocyte that is of T cell, B cell, or myeloid lineage in a human subject. Terstappen also fails to provide any teaching, suggestion, or motivation to combine or modify the teachings of the prior art to produce Applicants' claimed method. Terstappen teaches a method for classifying leukemias that uses different techniques and analyses and does not remotely suggest any desirability to combine the teachings therein with any other prior art to achieve Applicants' invention. Verwer teaches a method for classifying leukemias that also uses different techniques and analyses and does not suggest any desirability to combine the teachings therein with any other prior art to achieve Applicants' method for identifying a leukocyte that is of a T cell, B cell, or myeloid lineage. Thus, the cited documents lack the requisite suggestion or motivation to combine the teachings therein to obtain Applicants' claimed method.

Applicants therefore respectfully submit that the claims meet the requirements for nonobviousness under 35 U.S.C. § 103 and request that this rejection be withdrawn.

Claims 1, 2, 18, 19, and 21 also stand rejected under 35 U.S.C. § 103, allegedly for being obvious over Hoeffler (U.S. Publication No. 2002/0164656) in view of Terstappen (U.S. Patent No. 5,234,816). The Action alleges that Hoeffler, as evidenced in claim 28 therein, contemplates using known antibodies for diagnosing a disorder comprising contacting an array of antibodies that are specific for one or more antigens characteristic of a disorder. The Action also alleges that the present claims encompass use of cell lysates as well as whole cells.

Applicants respectfully traverse this ground of rejection and submit that the amended claims meet the requirements for nonobviousness. Applicants respectfully submit neither Hoeffler alone, nor Hoeffler in combination with Terstappen, teaches or suggests each and every limitation of the pending claims. Each cited document alone or in combination fails to teach or suggest a method for identifying a leukocyte that is of T cell, B cell, or myeloid lineage by contacting cells from a human subject with an array of immunoglobulin molecules that are immobilized to a solid surface and that are specific for cell surface marker antigens, comprising CD3, CD4, CD8, CD14, CD19, and CD56. Furthermore, neither document teaches a method for

identifying a leukocyte that is of T cell, B cell, or myeloid lineage, wherein a leukocyte associated with one lineage (*e.g.*, a T cell, B cell, or myeloid lineage) is distinguishable from a leukocyte associated with a different lineage, by determining differential binding density of immunoglobulins to the cell surface marker antigens, CD3, CD4, CD8, CD14, CD19, and CD56.

Hoeffler fails to teach a method that comprises immunoglobulins that are specific for CD antigens, which are cell surface antigens. Hoeffler also fails to teach or suggest contacting leukocytes in a biological sample with an array of immunoglobulin molecules, wherein the leukocytes express cell surface CD antigens. Hoeffler is silent with regard to using a sample containing intact cells, such as leukocytes, in the methods taught therein. Hoeffler teaches that antigens used in the method described therein are often proteins, although the antigens may be organic chemical compounds, carbohydrates, nucleic acids, and that the antigens may be isolated or semi-isolated, whether recombinantly made or naturally occurring (Hoeffler, paragraph 42). Terstappen fails to teach concurrent analysis of each immunoglobulin/antigen binding interaction and instead teaches a sequential analysis of antibody pairings.

Furthermore, Hoeffler fails to suggest, teach, or motivate a person having ordinary skill in the art to combine its teachings with any other prior art teaching to obtain the claimed method for identifying a leukocyte that is of T cell, B cell, or myeloid lineage with a reasonable expectation of success. Terstappen also fails to provide any teaching, suggestion, or motivation to combine or modify the teachings of the prior art to produce Applicants' claimed method. Terstappen teaches a method for classifying leukemias that uses different techniques and analyses and does not remotely suggest any desirability to combine the teachings therein with any other prior art to achieve Applicants' invention.

Accordingly, Applicants respectfully submit that the pending claims satisfy the requirements for nonobviousness under 35 U.S.C. § 103 and request that these rejections be withdrawn.

Applicants respectfully submit that pending claims 1, 2, and 18-21 are allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. In the event that the Examiner believes a teleconference will facilitate prosecution of this case, the Examiner is invited to telephone the undersigned at 206-622-4900.

Respectfully submitted,

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